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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,319

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Yoshinobu Watanabe

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EXAMINER

BOR, HELENE CATHERINE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,319	<b>Applicant(s)</b> WATANABE ET AL.	
	<b>Examiner</b> HELENE BOR	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Ultrasound Diagnostic Apparatus for Calculating Positions to Determine IMT and Lumen Boundaries.

### ***Claim Objections***

2. Claims 6, 8 & 17 are objected to because of the following informalities: The claims state, "a predetermined number or more". The language "or more" is unnecessary as a predetermined number is an undefined number. The words, "or more", don't further define the predetermined number and lead to a clumsy and confusing claim language. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim language such as "that transmits...from a skin surface...toward a blood vessel" and "receives an...echo reflected by the blood vessel" improperly include a body part, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 1-3 & 5-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hasegawa et al. (Hasegawa, H. et al., "Detection of lumen-intima interface of posterior wall for measurement of elasticity of the human carotid artery," *Ultrasonics, Ferroelectrics and Frequency Control, IEEE Transactions on* , vol.51, no.1, pp. 93-108, Jan 2004; copy enclosed herein).

**Claim 1, 7 & 9:** Hasegawa teaches an ultrasonic diagnostic apparatus, comprising a transmission unit that transmits at least one ultrasonic pulse from a skin surface of a subject toward a blood vessel thereof (Abstract). Hasegawa teaches an ultrasonic diagnostic apparatus, comprising a reception unit that receives an ultrasonic echo reflected by the blood vessel and converts the same into an electric signal to obtain a signal of the ultrasonic echo along a depth direction from the skin surface (Page 94 Section II Part B & C). Hasegawa teaches an ultrasonic diagnostic apparatus, comprising a movement detection unit that analyzes a phase of the ultrasonic echo signal in a direction traversing the blood vessel so as to calculate a movement amount in each of a plurality of parts included in a blood vessel wall constituting the blood vessel and a vicinity of the blood vessel wall (Figure 1, (2)). Hasegawa teaches an ultrasonic diagnostic apparatus, comprising a boundary detection unit that detects a boundary position between an inner membrane of the blood vessel and a blood flow region in a lumen of the blood vessel through which blood flows and a position of a

middle membrane of the blood vessel based on a variation in the calculated movement amount in each part (Page 99). Hasegawa teaches the ultrasonic diagnostic apparatus, wherein the measurement cycles include a heartbeat cycle of a blood flow that flows through the blood vessel (Figure 1, (2)).

**Claim 2 & 10:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising a ROI placement unit [tracking portion] that sets placement of a ROI where the boundary position along the depth direction from the skin surface is to be detected by the boundary detection unit (Figure 2 (a) & (b)). Hasegawa teaches the ultrasonic diagnostic apparatus, wherein the ROI placement unit places the ROI so as to lie over at least one of an anterior wall of the blood vessel wall on a side closer to the transmission unit and a posterior wall of the blood vessel wall on a side farther from the transmission unit (Figure 2 (a) & (b)).

**Claim 3:** Hasegawa teaches the ultrasonic diagnostic apparatus, wherein the transmission unit transmits a plurality of ultrasonic pulses toward a plurality of parts along a longitudinal direction of the blood vessel (Figure 2, l). Hasegawa teaches the boundary position detection unit detects the boundary position for each of the plurality of parts along the longitudinal direction of the blood vessel (Page 97).

**Claim 5, 19 & 20:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising a display unit that displays an image of the blood vessel in cross section along the longitudinal direction of the blood vessel based on the boundary position along the longitudinal direction of the blood vessel that is detected by the boundary position detection unit (Figure 2). Hasegawa teaches a unit that displays a value of the

thickness calculated by the calculation unit on a monitor (Page 97). Hasegawa teaches a unit that displays the boundary position and the position of the middle membrane detected by the boundary detection unit on a monitor (Figure 12, (b)). Hasegawa teaches a display unit that displays a part where a maximum thickness is measured among the thicknesses measured at the plurality of parts (Figure 4 (a) (b)).

**Claim 6:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising an average processing unit that performs average processing of data representing the boundary position that is detected by the boundary position detection unit based on data representing a boundary position obtained a predetermined number or more of measurement cycles before (Page 101 Section III Part A).

**Claim 8:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising an average processing unit that performs average processing of data representing the movement amount of the blood vessel wall that is detected by the movement detection unit based on data representing a movement amount obtained a predetermined number or more of measurement cycles before (Page 101 Section III Part A).

**Claim 11 & 12:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising a calculation unit that measures a thickness from the inner membrane to the middle membrane based on the boundary position and the position of the middle membrane (Figure 1, (3)). Hasegawa teaches the calculation unit measures the thickness from the inner membrane to the middle membrane based on a variation over time in the boundary position and a variation over time in the position of the middle membrane in one heartbeat cycle ((Figure 1, (2) (3)).

**Claim 13 & 14:** Hasegawa teaches the ultrasonic diagnostic apparatus, wherein the calculation unit calculates at least one of a maximum value, a minimum value and an average value of the thickness in one heartbeat cycle (Page 105) and measures the thickness at each of the plurality of parts (Page 96 Section B Part 1).

**Claim 16:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising an angle correction unit that performs angle correction with respect to a value of the thickness corresponding to an angle formed between a measuring direction of the thickness calculated by the calculation unit and a direction perpendicular to the blood vessel wall (Page 98).

**Claim 17 & 18:** Hasegawa teaches the ultrasonic diagnostic apparatus, further comprising a stability determination unit that determines stability of the thickness calculated by the calculation unit by comparing the thickness calculated by the calculation unit with a thickness obtained a predetermined number or more of cycles before (Figure 11).

***Claim Rejections - 35 USC § 103***

6. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa et al. and further in view of Li'756 (US Patent Application No. 2003/0114756 A1).

**Claim 4:** Hasegawa teaches the ultrasonic diagnostic apparatus, for processing of data representing the boundary position along the longitudinal direction of the blood vessel that is detected by the boundary position detection unit (Page 99). Hasegawa fails to teach the filter. However, Li'756 teaches a filter processing unit [wall filter] (Page 2, Para 21-23). It would have been obvious to one of ordinary skill in the art to combine

the teachings of Hasegawa and Li'756 in order to remove motion artifacts (Page 3, Para 23).

### ***Response to Arguments***

7. Applicant's arguments, see Page 8, filed 11/09/2007, with respect to the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn.

8. Applicant's arguments, see Page 8, filed 11/09/2007, with respect to the rejection(s) of claim(s) 1-3 & 5-20 under 35 USC § 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hasegawa, H. et al., "Detection of lumen-intima interface of posterior wall for measurement of elasticity of the human carotid artery," *Ultrasonics, Ferroelectrics and Frequency Control, IEEE Transactions on* , vol.51, no.1, pp. 93-108, Jan 2004.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

hcb